

Application No. 10/521,823

Amendment and Response Accompanying a RCE dated August 11, 2010

Further Reply to Office Action of May 11, 2010, and

Reply to Advisory Action of August 5, 2010

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application. Please amend the claims as follows:

1. (Currently amended) An oral dosage delivery vehicle comprising an edible film including a uniformly distributed active ingredient, wherein said film comprises ~~dosage units releasably joined by one or more weakened sections, which permit said dosage units to be detached from said film~~weakened sections which divide the film into segments that represent individual dosage units.
2. (Original) The delivery vehicle of claim 1, wherein said film is self-supporting.
3. (Original) The delivery vehicle of claim 1, wherein said weakened sections are perforations.
4. (Original) The delivery vehicle of claim 1, wherein said weakened sections are scored.
5. (Original) The delivery vehicle of claim 1, wherein said active is a pharmaceutical or cosmetic active.
6. (Original) The delivery vehicle of claim 1, wherein said active varies no more than 10% among said dosage units.
7. (Original) The delivery vehicle of claim 1, wherein said film includes a carrier layer of a substantially water insoluble material.

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8. (Original) The delivery vehicle of claim 1, wherein the film has a surface with a surface area comprising voids that increase the surface area.

9. (Original) The delivery vehicle of claim 8, wherein said voids increase the speed of dissolution of said delivery vehicle.

10. (Original) The delivery vehicle of claim 8, wherein the voids are selected from the group consisting of voids that go through the entire depth of the film, voids that go through a portion of the depth of the film, and voids that are formed by casting the film on a patterned template.

11. (Withdrawn – Currently amended) An oral dosage delivery vehicle comprising an edible film, wherein said film comprises ~~dosage units releasably joined by one or more weakened sections, which permit said dosage units to be detached from said film~~ weakened sections which divide the film into segments that represent individual dosage units.

12. (Withdrawn) The delivery vehicle of claim 11, wherein said weakened sections contain less film composition than surrounding areas.

13. (Withdrawn) The delivery vehicle of claim 11, wherein said film is self-supporting.

14. (Withdrawn) The delivery vehicle of claim 11, wherein said weakened sections are perforations.

15. (Withdrawn) The delivery vehicle of claim 11, wherein said weakened sections are scored.

16. (Original) The delivery vehicle of claim 11, further comprising an active ingredient.

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17. (Original) The delivery vehicle of claim 16, wherein said active is uniformly distributed.

18. (Withdrawn) The delivery vehicle of claim 11, wherein said film includes a carrier layer of a substantially water insoluble material.

19. (Original) The delivery vehicle of claim 17, wherein the film has a surface with a surface area comprising voids that increase the surface area.

20. (Original) The delivery vehicle of claim 19, wherein the voids are selected from the group consisting of voids that go through the entire depth of the film, voids that go through a portion of the depth of the film, and voids that are formed by casting the film on a patterned template.

21. (Withdrawn) A package for the storage and dispensing of a sheet-like rapid dissolve dosage form, comprising:

a) a pouch comprising a top layer and a bottom layer each having an outer edge, wherein said top and bottom layers are sealed at the respective outer edges to define an enclosed interior surface therewithin, and

b) a sheet-like rapid dissolve dosage form contained within said enclosed space.

22. (Withdrawn) The package of claim 21, wherein said dosage form includes an active ingredient and comprises a sheet of one or more dosage forms.

23. (Withdrawn) The package of claim 22, wherein said dosage form includes weakened sections.

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24. (Withdrawn) The package of claim 22, wherein said weakened sections include perforations.

25. (Withdrawn) The package of claim 23, wherein said weakened sections form one or more equally spaced lines in a direction selected from vertical, horizontal, and combinations thereof.

26. (Withdrawn) The package of claim 21, wherein said pouch is resealable.

27. (Withdrawn) A method of storing a sheet-like rapid dissolve dosage form comprising the steps of:

- a) preparing a sheet-like dosage form that includes an active ingredient;
- b) defining said dosage form into a plurality of substantially equal weakened sections separable dosage units by forming in said dosage form;
- c) preparing a pouch comprising top and bottom layers each having an outer edge;
- d) placing said dosage form between said top and bottom layers; and
- e) sealing the outer edges of said pouch.

28. (Withdrawn) A method of dispensing a sheet-like dosage form comprising the steps of:

- a) preparing a sheet-like dosage form that includes an active ingredient;
- b) separating said dosage form by weakened sections into segments of substantially equal area;
- c) preparing a pouch comprising top and bottom layers each of said layers having an edge surrounding the circumference of said layer;
- d) placing said dosage form between said top and bottom layers;
- e) separably sealing a portion of said edges of said pouch;
- f) opening a portion of said pouch;

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g) opening one or more of said sections of said dosage form along said perforations;
and

h) removing said one or more segments from said pouch.